complex with at least one cyclodextrin; wherein said anthelmintically active compounds is 5-oximino-22, 23-dihydro-25-cyclohexylavermectin B1 monosaccharide.

20. (NEW) The pharmaceutical composition of claim 19, wherein the cyclodextrin is  $\alpha$ -,  $\beta$ - or  $\gamma$ -cyclodextrin, or a derivative or mixture thereof.

## **REMARKS**

The Examiner is thanked for having graciously held a telephone interview with the undersigned on July 30, 2003.

The application and the Office Action of June 16, 2003 were discussed. It was agreed that new claims 6 and 7 filed with Applicants' March 31, 2003 Amendment should be renumbered as new claims 19 and 20, respectively. It was also agreed that the rejection of claims 3-5, 19 and 20 be reconsidered.

Claims 1-5 were pending in the present application. Claims 1 and 2 are cancelled without prejudice. Claim 3 is amended to be an independent claim. New claims 19 and 20 are added.

The amendment to claim 3 involves change its dependency and does not raise any issue of new matter. New claims 19 and 20 are renumbered from new claims 6 and 7 introduced in Applicants' March 31, 2003 Amendment. Applicants contend that the present Amendment is fully supported by the original specification and does not raise any issue of new matter. Moreover, the present Amendment would place all pending claims in condition for allowance or simplify issues for appeal. Therefore, entry of the present Amendment is respectfully requested. Upon entry of the present Amendment, claims 3-5, 19 and 20 will be under examination.

## CLAIM REJECTION UNDER 35 U.S.C. §103(a)

Claims 1-5 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Loftsson, U.S. Patent No. 5,472,954 ("Loftsson") in combination with Asato, U.S. Patent No. 4,886,829 ("Asato"). The Office Action asserts that "Asato teaches the compound of formula I and also teaches that the compounds of this formula are antihelmintic compounds which may be formulated in liquid or solid form for infestation in warm blooded animals and agriculture." *Office Action at page 2*.

Applicants respectfully point out that there is no teaching or suggestion that Asato and Loftsson can be combined. Even if they are combined, the combination does not teach "all the claim limitations" as required by M.P.E.P. §2143.01 to establish a *prima facie* case of obviousness. Applicants note that this requirement does not contradict the Examiner's

statement that "Applicant should note that if Loftsson reference contained all of the elements of the claim, then a 35 U.S.C. 102 would be applicable." For a proper rejection under 35 U.S.C. 102, all elements of the claim have to be found in a single reference. In the context of obviousness rejection over a combination of references, M.P.E.P. §2143.01 simply requires that the combination teach "all the claim limitations."

In this case, the Asato-Loftsson combination does not disclose "all the claim limitations" of claims 3-5, 19 and 20. Specifically, the Asato-Loftsson combination does not disclose formula I. Nor does the Asato-Loftsson combination specifically disclose "5-oximino-22, 23-dihydro-25-cyclohexylavermectin B1 monosaccharide" and its combination with " $\alpha$ -,  $\beta$ - or  $\gamma$ -cyclodextrin, or a derivative or mixture thereof." Applicants contend that the Office Action fails to satisfy the requirement of M.P.E.P. §2142 for establishing a *prime facie* case of obviousness.

Moreover, even assuming that the Asato-Loftsson combination does disclose the use of cyclodextrins to increase the solubility and stability of all sorts of cosmetic additives and agrochemicals listed in column 8 of Loftsson, such disclosure only amounts to a suggestion of general approach that seemed to be a promising field of experimentation. Based on such disclosure, one of ordinary skill in the art would have to use "try and error" approach to formulate the claimed composition. However, the Federal Circuit Court has held in *In re O'Farrell*: 7 U.S.P.Q. 2d 1673, 1681 at 1681 (Fed. Cir. 1988) that such an "obvious to try" rejection is not permissible.

Therefore, claims 3-5, 19 and 20 are nonobvious over the combination of Asato and Loftsson. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

## CONCLUSION

In view of the claim amendments and the remarks, Applicants believe that present Amendment addresses all outstanding issues of the Office Action. Further and favorable consideration of the present application and the issuance of a Notice of Allowance with regard to all pending claims are respectfully requested.

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It is believed that no fee is deemed necessary in connection with the filing of the present Amendment. However, if any fees are required, the Examiner is authorized to charge any such fees to our Deposit Account No. 16-1445.

Date: 12/15/03

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